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Review Article

Orodispersible Film Technology: Advances in Rapidly Dispersible Drug Delivery Systems Using Natural and Synthetic Polymers

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Abstract:

Orodispersible film technology has emerged as one of the most impactful innovations in oral drug delivery, particularly for patient populations who experience difficulty in swallowing conventional solid dosage forms. This article provides a comprehensive account of orodispersible films, encompassing their classification, compositional framework, manufacturing processes, and the pivotal role of natural polymers in advancing formulation science. The review examines flash-release, mucoadhesive melt-away, and mucoadhesive sustained-release film categories, each distinguished by distinct release mechanisms and polymer architectures. Specific attention is directed toward the unique advantages of natural polysaccharides — pullulan, sodium alginate, chitosan, and pectin — which confer biocompatibility, mucoadhesion, and controlled release characteristics while aligning with sustainability objectives. Manufacturing strategies including solvent casting, semi-solid casting, hot melt extrusion, spray coating, and emulsion solvent evaporation are described with a focus on their mechanistic basis and scalability. The review concludes that orodispersible films represent a scientifically mature, commercially viable, and patient-centric drug delivery platform whose potential is still expanding through natural polymer integration and innovative fabrication approaches.

Keywords: orodispersible films, natural polymers, mucoadhesion, solvent casting, flash release, sustained release, drug delivery, pullulan, chitosan, patient compliance.

Introduction

The oral route remains the dominant and most widely preferred pathway for drug administration, owing to its simplicity, non-invasiveness, and superior patient acceptability [1]. Both solid formulations including tablets, capsules, and films — and liquid preparations such as syrups, suspensions, and elixirs constitute the arsenal of oral dosage forms. Among solid forms, conventional tablets and capsules demand intact deglutition, a physiological function that is compromised in a substantial proportion of the global population, particularly children, elderly individuals, and patients suffering from dysphagia, neurological disorders, or throat-related conditions [2]. Such patients frequently report fear of choking during medication intake, leading to reduced adherence and compromised therapeutic outcomes.

To overcome these barriers, pharmaceutical scientists have developed rapidly dispersible dosage systems based on the principle of fast disintegration, wherein the formulation dissolves in the oral cavity within seconds, eliminating any dependence on water or deliberate swallowing [3]. Among these, thin oral films — also referred to as orodispersible films (ODFs) or orodispersible films have emerged as a technologically elegant solution. When placed on the tongue or the oral mucosa, these films undergo rapid hydration and dissolution through contact with saliva, releasing the active pharmaceutical ingredient for local action or systemic absorption [4].

A pharmacokinetically significant feature of orodispersible film delivery is the capacity to bypass hepatic first-pass metabolism. The oral mucosal tissue, particularly the sublingual region, is richly supplied with capillaries, and drugs absorbed here enter the systemic circulation directly without undergoing presystemic hepatic clearance [5]. This characteristic is especially advantageous for drugs with poor oral bioavailability due to extensive hepatic metabolism, as oral mucosal delivery significantly enhances their plasma concentrations and onset of action compared to conventional oral or even parenteral routes [6]. Drug transport across the oral mucosa primarily proceeds via transcellular and paracellular mechanisms: hydrophilic molecules traverse intercellular aqueous channels, while

lipophilic compounds penetrate the lipid bilayer of mucosal cells [10]. The increasing interest in natural polymer-based ODFs represents a particularly exciting development. Biopolymers such as cellulose derivatives, pullulan, chitosan, and sodium alginate offer inherent biocompatibility, biodegradability, and versatile functionalization for controlled drug release [17]. These materials simultaneously address environmental sustainability concerns and fulfil patient safety standards, making them attractive for both industrial-scale manufacturing and patient-centric formulation design [18].

Types of Rapidly Dispersible Drug Delivery Systems: Although the oral route dominates drug administration, the oral mucosal route has gained recognition as a clinically valuable alternative, particularly for drugs requiring pre-gastric absorption or for patients with swallowing difficulties. Several categories of rapidly dispersible systems are currently in use or under active development [7].

Fast-Dissolving Oral Disintegrating Tablets: Orally disintegrating tablets (ODTs) are manufactured using direct compression, employing water-soluble excipients combined with super disintegrants or effervescent agents to achieve rapid tablet breakdown upon oral contact [2]. The manufacturing process influences the product's friability and hardness. Although ODTs can accommodate a substantial drug payload and taste-masking materials, their disintegration time is generally longer compared to oral films, which limits their utility in patients with severe dysphagia [3].

Thin Oral Films and Wafers: Thin oral films, also termed oral wafers in contemporary literature, are flat, flexible polymeric matrices that are placed in the oral cavity for rapid dissolution. Despite being a relatively recent innovation, they have attracted significant industrial interest due to their compact size and fast-release characteristics [7]. These films are fabricated from hydrophilic polymers and may contain soluble or insoluble compounds, as well as taste-masked active ingredients. Following casting and drying, large sheets are precision-cut into unit-dose strips of pharmaceutically appropriate dimensions, typically 50–200 mm², allowing for accurate dosing [11].

Lyophilised Systems: Lyophilised or freeze-dried oral wafers are produced by dispensing liquid drug-containing mixtures into tablet-shaped moulds, followed by freezing and lyophilisation. The resulting highly porous structure permits rapid water penetration and disintegration on contact with saliva, mimicking fast-dissolving film behaviour. Taste masking agents can be incorporated, and dose handling capacity varies with drug solubility characteristics [12].

Orodispersible Films: Orodispersible films are thin, postage-stamp-sized adhesive matrices applied to the oral mucosa, where they hydrate and release drug over a defined period. These films have received regulatory approval in the United States and Japan and are formulated using mucoadhesive polymers that maintain film residence on the mucosal surface [6]. Compared to oral mucosal tablets and oral gels, orodispersible films are preferred for their flexibility, comfort, and prolonged contact time, which promotes sustained drug absorption. Additionally, their wound-protecting capability renders them useful in oral disease management [9].

Bi-layer orodispersible films represent a sophisticated design strategy that allows simultaneous delivery of two drugs — or the same drug with dual release kinetics. One layer may be engineered for immediate release to generate a rapid therapeutic response, while the second functions as a sustained-release reservoir, providing prolonged drug delivery over several hours [13].

Types of Orodispersible Films

Orodispersible films are classified into three functional categories based on their release mechanisms and structural composition [6]:

- **Flash-release films:** Single-layered, small-area constructs (2–8 cm²) that disintegrate within 60 seconds of placement on the tongue. Suitable for achieving rapid local or systemic pharmacological effects.
- **Mucoadhesive melt-away films:** Single or multi-layered films that adhere to the oral mucosa and dissolve over several minutes. Designed for applications requiring a modestly prolonged drug release profile.
- **Mucoadhesive sustained-release films:** Multi-layered constructs (2–4 cm²) incorporating non-dissolvable polymers to sustain drug release over extended periods of up to 8–10 hours. Ideal for chronic conditions requiring controlled orodispersible drug delivery.

Composition of Buccal Films: Orodispersible films are multi-component systems in which the choice of each excipient critically influences the mechanical, release, and sensory properties of the final product. The recommended drug loading per unit dose generally does not exceed 30 mg, and the total film area ranges from 1 to 20 cm² depending on dose requirements [13]. The general quantitative composition of a typical rapidly dispersible oral film is presented in Table 1.

Table 1: General Composition of Rapidly Dispersible Thin Oral Films [9,13]

Ingredient	Proportion (% w/w)
Water-soluble film-forming polymers	45–50
Active pharmaceutical ingredient (API)	5–30
Plasticiser	0–20
Sweetening agents	3–7
Salivary stimulants (acidic agents)	2–5
Surfactants	As required (q.s.)
Flavours and colourants	q.s.

Film-Forming Polymers: Film-forming polymers constitute the structural backbone of orodispersible films. Their type and concentration determine the film's durability, flexibility, and disintegration behaviour [16]. A wide range of both natural and synthetic polymers is available, and they may be used individually or in combination to optimise the film's physicochemical profile.

Pullulan is a natural, water-soluble polysaccharide composed of maltotriose repeat units connected by alpha-1,6 glycosidic bonds. Its amorphous structure confers excellent film-forming ability, producing clear, tasteless, flexible films with high transparency. Pullulan initiates thermal decomposition at approximately 250 °C and is soluble in aqueous and alkaline media [14]. Its GRAS (Generally Recognised As Safe) status makes it particularly attractive for paediatric and geriatric ODF formulations.

Gelatin, a protein derived from the alkaline or acid hydrolysis of animal collagen, is available in Type A (acid-treated) and Type B (alkali-treated) forms. Its film-forming capacity is directly correlated with molecular weight, and it imparts a smooth mouthfeel and excellent flavour-carrier properties to the film matrix [14]. Gelatin films exhibit rapid dissolution kinetics, making them well suited for flash-release ODF formulations.

Sodium alginate, the sodium salt of alginic acid derived from brown seaweed, is characterised by high water solubility and distinctive colloidal properties including viscosity modification, emulsion stabilisation, and gel formation. Its interaction with divalent salivary ions (calcium) enhances mucoadhesion and extends film residence time on the mucosa [10]. Blending sodium alginate with starch further improves the mechanical strength of the resulting films.

Chitosan is a deacetylated derivative of chitin possessing a glycopyranose ring structure. Its cationic nature at physiological pH enables electrostatic interaction with the negatively charged mucin glycoproteins of the oral mucosa, producing strong mucoadhesion and permeation-enhancing effects [19]. Chitosan films demonstrate uniform thickness, compactness, and cohesion, and their inherent antimicrobial activity adds a functional advantage in oral disease management.

Hydroxypropyl methylcellulose (HPMC) is a semi-synthetic cellulose derivative with outstanding film-forming ability, producing transparent, flexible films with good moisture resistance [16]. Low-viscosity grades (E3, E5, E15) are preferred for ODF applications as they produce films with rapid wetting and dissolution without compromising structural integrity [16].

Polyvinyl alcohol (PVA) is a synthetic polymer produced by the partial or complete hydrolysis of polyvinyl acetate. It is water-soluble, exhibits excellent film-forming properties, and provides films with high tensile strength, good oxygen barrier characteristics, and flexibility. PVA is considered biodegradable under specific environmental conditions, supporting sustainability in pharmaceutical manufacturing [20].

Polyvinylpyrrolidone (PVP), a synthetic polymer composed of N-vinylpyrrolidone repeat units, is highly soluble in water and polar solvents. Its hygroscopic nature and strong hydrogen bonding capacity make it effective as a film-former, binder, and solubility enhancer for poorly water-soluble drugs in ODF formulations [20].

Active Pharmaceutical Ingredients (APIs): The selection of a suitable API for orodispersible film incorporation requires careful consideration of pharmacokinetic, physicochemical, and organoleptic criteria [7]. Drugs with low therapeutic doses, low molecular weights (generally < 500 Da), and favourable salivary solubility are preferred candidates. The drug content within the film matrix typically ranges from 5 to 30% w/w [7]. Orodispersible films have successfully incorporated APIs spanning a wide therapeutic spectrum: antihistamines, antitussives, antiepileptics, antiemetics, antifungals, cardiovascular drugs, anxiolytics, drugs for erectile dysfunction, and central nervous system agents [8].

Hydrophilic drugs are dissolved directly into the polymer solution prior to casting, while hydrophobic drugs are micronised, encapsulated into nanoparticles, or dispersed within the polymeric matrix to enhance release [15]. Sparingly soluble drugs can be incorporated as salt forms or cyclodextrin complexes to improve solubility. Even drugs with limited oral mucosal permeability may benefit from ODF delivery, as

rapid dissolution in the oral cavity facilitates swift gastrointestinal absorption post-swallowing [12].

Plasticisers: Plasticisers are incorporated into orodispersible film formulations to reduce polymer chain rigidity, lower the glass transition temperature (Tg), and impart mechanical flexibility. They typically constitute 0–20% w/w of the total dried polymer weight [13]. Commonly used plasticisers include glycerol, propylene glycol, PEG-400, PEG-600, PEG-2000, sorbitol, and castor oil. Proper plasticiser selection — guided by polymer compatibility and solvent type — is essential to prevent film cracking, splitting, and edge peeling during manufacture and storage [9].

Sweeteners and Flavours: Taste masking is a critical formulation requirement for orodispersible films, as drug dissolution occurs in direct contact with taste receptor-bearing mucosal surfaces [8]. Natural sweeteners such as glucose, fructose, and maltose are employed at 3–6% w/w; fructose is particularly favoured for its high sweetening intensity relative to mannitol and sorbitol. Artificial sweeteners including acesulfame potassium (200× sweeter than sucrose), sucralose (600×), neotame (2000×), and alitame (8000×) are used in low quantities for maximum taste correction [3]. Approved flavours — mint, fruit, and confectionery types — complement sweetener action via psychosensory override of residual bitter taste.

Salivary Stimulants and Surfactants: Rapid and complete film disintegration depends on sufficient salivary volume in the oral cavity. Salivary stimulants — citric acid, lactic acid, ascorbic acid, malic acid, and tartaric acid — are incorporated to promote saliva secretion reflexively upon film contact, thereby accelerating film wetting and dissolution [11].

Surfactants such as poloxamer 407, sodium lauryl sulphate, Tween 80, and propylene glycol serve to solubilise hydrophobic components, enhance wetting, and improve drug dispersion within the film matrix [10].

Table 2 summarises the key performance attributes of orodispersible films as compiled from the literature.

Table 2: Key Performance Attributes of Orodispersible Film Drug Delivery Systems [1,4,6,9]

Attribute	Description
Form factor	Thin, flexible strip; different sizes and shapes; area 1–25 cm²
Water requirement	Minimal or none; self-dissolving on contact with saliva
Disintegration	Rapid; typically, 1–60 seconds depending on film type
Mucoadhesion	Optional; incorporated via mucoadhesive polymers for prolonged residence
Dose accuracy	Precise unit-dose strip; superior to liquid formulations
Patient suitability	Paediatric, geriatric, dysphagic, and non-compliant patients
Stability	Solid-state; thermodynamically stable relative to liquids

Manufacturing Techniques of Buccal Films: Multiple manufacturing approaches are employed in the preparation of orodispersible films, each selected based on the physicochemical properties of the drug, the desired film characteristics, and practical scalability considerations [7]. The principal techniques are described below.

Solvent Casting Technique: Solvent casting is the most widely adopted method for orodispersible film preparation in both laboratory and industrial settings.

The process begins with dissolution of film-forming polymers in an appropriate solvent — commonly water, ethanol, or aqueous-alcoholic mixtures — followed by incorporation of the drug, plasticiser, sweeteners, flavours, and other excipients to yield a homogeneous casting solution [15]. This solution is cast onto a flat, inert substrate — glass, stainless steel, or polyester film — using a doctor blade or controlled-gap spreader to produce a wet film of defined thickness. Solvent evaporation proceeds under controlled temperature and humidity conditions, after which the dried film is carefully delaminated, inspected, and cut into unit-dose strips. The method yields flexible, uniform films with excellent drug distribution and reproducible dissolution behaviour [1].

Semi-Solid Casting Method: In semi-solid casting, the drug and excipients are dissolved together and homogenised using a magnetic stirrer, then allowed to de-aerate for approximately 8 hours prior to casting in Petri dishes. Drying is conducted in a hot-air oven at 45–50 °C, and the resulting film is peeled and cut to appropriate dimensions for characterisation. This method is particularly advantageous for thermolabile drugs and for formulations in which film toughness and mucoadhesive characteristics are prioritised [14].

Hot Melt Extrusion: Hot melt extrusion (HME) is a solvent-free, continuous process in which drug and polymer are blended in defined ratios, melted under controlled temperature and pressure in a heated barrel, and extruded through a flat film die [14]. The extrudate is rapidly cooled to solidify into a thin film of consistent thickness. HME is environmentally advantageous due to the absence of organic solvents and produces amorphous solid dispersions of poorly water-soluble drugs that

exhibit enhanced dissolution rates. A related technique, solid dispersion extrusion, was used to prepare domperidone orodispersible films incorporating HPMC E15, PEG 400, and beta-cyclodextrin as solubilising excipients, demonstrating the versatility of HME-based ODF manufacturing [14].

Spray Coating Technique: In spray coating, a drug-polymer solution is atomised using a spray nozzle and deposited uniformly onto a substrate such as Teflon sheeting, Kraft paper, or glass plates. After controlled drying, the polymer film is separated from the substrate as a free-standing oral film [15]. This technique offers excellent control over film thickness and uniformity and is amenable to continuous manufacturing integration. It is particularly suitable for films incorporating permeation enhancers or functional coating layers.

Emulsion Solvent Evaporation: The emulsion solvent evaporation method is employed primarily for lipophilic drugs or where a biphasic polymer system is desired. The drug is dispersed in a polymer solution (internal phase) that is emulsified into an aqueous continuous phase containing an emulsifying agent using a high-shear or ultrasonic homogeniser. Gentle heating or ambient evaporation removes the solvent, depositing a thin film containing uniformly distributed drug and polymer at the substrate interface [7]. This technique supports the incorporation of hydrophobic drugs without the need for solubilising agents that might compromise film taste or stability.

Natural Polymer-Based Orodispersible Films: The growing impetus toward sustainable and biocompatible pharmaceutical materials has elevated natural polysaccharides to a position of central importance in ODF development. Natural polymers offer a combination of inherent biological activity — mucoadhesion, permeation enhancement, antimicrobial properties — and environmentally favourable profiles that synthetic polymers often cannot match. Their ability to form stable, flexible films with controlled release kinetics positions them as preferred materials for next-generation ODF platforms [17].

Pullulan-Based Films: Pullulan's outstanding film-forming capacity produces transparent, odourless films with rapid disintegration kinetics that are especially well-suited to paediatric and geriatric applications. Studies of pullulan-based loratadine ODFs have demonstrated effective rapid absorption of the antihistamine in clinical evaluations, with patient and caregiver preference significantly favouring the film format over conventional tablets or syrups [14]. The natural origin of pullulan and its GRAS designation further enhance its regulatory acceptance for paediatric formulations.

Sodium Alginate Films: Sodium alginate's gel-forming properties in the presence of salivary calcium ions produce a viscoelastic mucoadhesive layer that prolongs film-mucosal contact, supporting controlled drug release. In-vivo studies of sodium alginate–based ibuprofen ODFs have demonstrated enhanced drug retention in the oral cavity, with a controlled release profile extending analgesic action compared to immediate-release formulations [10]. The combination of alginate with starch in film matrices has been shown to further enhance tensile strength and puncture resistance.

Chitosan Films: The cationic charge of chitosan at physiological pH drives electrostatic adhesion to the anionic mucosal surface, creating a bioadhesive interface that significantly extends film residence time and drug absorption window. Chitosan-based acyclovir ODF studies have reported prolonged antiviral drug presence on mucosal surfaces, with in-vivo data confirming superior local drug concentrations compared to conventional topical preparations [19]. Chitosan's permeation-enhancing effect — mediated by transient opening of intercellular tight junctions — additionally boosts drug bioavailability for molecules with limited mucosal permeability.

Pectin-Based Films: Pectin, a complex anionic polysaccharide derived from plant cell walls, forms soft, flexible gels in the presence of divalent cations, producing ODF matrices with comfortable mouthfeel and controlled drug release characteristics. Clinical evaluations of pectin-based nicotine orodispersible films have demonstrated improved bioavailability and patient acceptability compared to nicotine gum, attributable to the controlled mucosal drug release profile and the absence of the mechanical chewing requirement [18]. Table 3 summarises key examples of natural polymer-based ODFs with their formulation characteristics and reported clinical outcomes.

Table 3: Natural Polymer-Based ODFs — Formulation Characteristics and Clinical Outcomes [10,14]

Film Type	Polymer	Model Drug	Key Property	Reported Outcome
Pullulan-based	Pullulan	Loratadine	Transparent; fast disintegration	Rapid absorption; child-friendly
Sodium alginate	Sodium alginate	Ibuprofen	Mucoadhesive; controlled release	Enhanced oral cavity drug retention
Chitosan-based	Chitosan	Acyclovir	Strong mucoadhesion; permeation-enhancing	Prolonged mucosal drug presence
Pectin-based	Pectin	Nicotine	Gel-forming; soft texture	Improved bioavailability via oral mucosa

The versatility of natural polymers across ODF film types from immediate-release pullulan systems to mucoadhesive chitosan platforms underscores their capacity to address the full spectrum of clinical ODF requirements. Their alignment with patient-centric and sustainability-oriented pharmaceutical development philosophies further reinforces their role as cornerstone materials in advancing ODF technology toward broader therapeutic and commercial application [17,20].

Conclusion

Orodispersible films represent a mature yet continuously evolving drug delivery technology with a well-established scientific and clinical foundation. Their capacity to dissolve rapidly in the oral cavity without water, bypass hepatic first-pass metabolism, and accommodate patient populations with swallowing difficulties positions them as one of the most patient-centric dosage forms available to contemporary pharmaceutical science. The integration of natural polymers — pullulan, sodium alginate, chitosan, and pectin — has expanded the functional repertoire of ODF platforms, enabling mucoadhesive, controlled-release, and biocompatible film systems that align with both patient safety requirements and environmental sustainability goals. Continued innovation in manufacturing processes, particularly the development of continuous-manufacturing-compatible solvent casting and hot melt extrusion platforms, will further enhance the scalability and quality consistency of orodispersible film production. As regulatory frameworks evolve to specifically address ODFs, and as clinical acceptability data accumulate across diverse patient populations, orodispersible film technology is poised to expand its therapeutic reach across an increasingly broad spectrum of pharmaceutical and nutraceutical applications.

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